



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-Z-0025]

### Medical Devices; Class I Surgeon's and Patient Examination Gloves

**AGENCY:** Department of Health and Human Services (HHS), Food and Drug Administration (FDA).

**ACTION:** Final order, determination.

**SUMMARY:** The Department of Health and Human Services (HHS or “the Department”) issued a Notice in the *Federal Register* of January 15, 2021, (“the January 15 notice”) which identified seven types of reserved class I devices that the Department had determined no longer require premarket notification. The Department and the Food and Drug Administration (FDA or “the Agency”) issued a Notice in the *Federal Register* of April 16, 2021 (“the April 16 notice”) explaining the basis for our current view that the seven types of reserved class I devices identified in the January 15 notice require a premarket notification, and explaining why the reasoning supporting the prior determination was unsound. HHS and FDA sought comment on the matters discussed in the April 16 notice, and have considered the comments that were submitted to the docket. HHS and FDA are issuing this final order and determination that the seven types of class I surgeon's gloves and patient examination gloves listed in the January 15 notice are reserved class I devices for which a premarket notification is required.

**DATES:** *Compliance date:* All devices subject to this order shall comply with the order no later than [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*.]

**ADDRESSES:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Angela Krueger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1660, Silver Spring, MD 20993, 301-796-6380, or by email at [RPG@fda.hhs.gov](mailto:RPG@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

I. Background Regarding Section 510(l) of the FD&C Act

Under section 513 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. The Medical Device Amendments of 1976 (“1976 amendments”) (Pub. L. 94-295), and the Safe Medical Devices Act of 1990 (Pub. L. 101-629), require FDA to classify devices into class I (“general controls”) if there is information showing that the general controls of the FD&C Act are sufficient to assure safety and effectiveness; into class II (“special controls”), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life sustaining or life supporting device, or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Unless a device is exempt from premarket notification, section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and the implementing regulations, part 807 of Title 21 of the Code of Federal Regulations (CFR), require persons who intend to market a new device to submit a premarket notification (510(k)) demonstrating the new device is “substantially equivalent” within the meaning of section 513(i) of the FD&C Act to a legally marketed device for which premarket

approval is not required. Section 510(l)(1) of the FD&C Act, added to the statute by the Food and Drug Administration Modernization Act of 1997 (FDAMA), provides that a 510(k) is not required for a class I device, except for any class I device intended for a use that is of substantial importance in preventing impairment of human health, or any class I device that presents a potential unreasonable risk of illness or injury. FDA refers to these as the “reserved criteria” and to class I devices subject to 510(k) as “class I reserved devices.” Thus, class I devices are exempt from the 510(k) requirements except for class I device types that meet the reserved criteria under section 510(l)(1).

As discussed in the April 16 notice, since 2017, FDA has evaluated which devices meet the reserved criteria several times. See 86 FR 20167 at 20168. Each time, FDA has made its determinations available to the public through publication in the *Federal Register*. See 63 FR 5387, 63 FR 63222, 65 FR 2296, 82 FR 17841, 84 FR 71794. In 1998, after FDAMA was enacted, FDA evaluated all class I devices in interstate commerce at that time, and published a notice in the *Federal Register* containing: (1) a list of device types that FDA believed met the reserved criteria and thus would remain subject to premarket notification and (2) a list of device types that FDA believed did not meet these criteria and thus would be exempt from such requirements. See 63 FR 5387. Although devices that did not meet the reserved criteria became exempt on February 19, 1998, FDA also issued proposed and final rules amending the applicable classification regulations for these devices, as well as for five device types that FDA had exempted prior to FDAMA that, post-FDAMA, FDA determined meet the reserved criteria. See 63 FR 63222, 65 FR 2296.

On December 13, 2016, the 21<sup>st</sup> Century Cures Act (Cures Act) amended section 510(l) of the FD&C Act, reorganizing section 510(l) into paragraphs 510(l)(1) and (2). Section 510(l)(2) of the FD&C Act requires FDA to identify at least once every 5 years, through publication in the *Federal Register*, any type of class I device that the Agency determines no longer requires a report under section 510(k) of the FD&C Act to provide reasonable assurance

of safety and effectiveness. Section 510(l)(2) of the FD&C Act further provides that, upon publication of the Agency's determination in the *Federal Register*, these devices shall be exempt from 510(k), and the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption. Accordingly, in 2017, FDA published in a notice in the *Federal Register* a list of class I device types that it has determined no longer meet the reserved criteria and are thus exempt from 510(k) (82 FR 17841). In 2019, FDA amended the classification regulations to reflect its exemption determinations.

## II. Criteria for Exemption from Section 510(k) of the FD&C Act

Section 510(l)(1) of the FD&C Act provides that a class I device is not exempt from the premarket notification requirements of section 510(k) of the FD&C Act if the device is intended for a use that is of substantial importance in preventing impairment of human health, or it presents a potential unreasonable risk of illness or injury. As explained in the April 16 notice, section 510(l)(2) of the FD&C Act directs FDA to identify which class I devices that FDA previously determined meet the reserved criteria no longer meet these criteria, in which case a 510(k) is no longer required to provide reasonable assurance of safety and effectiveness. FDA has explained that in determining whether either of these criteria are met, the Agency considers, for example, its experience in reviewing premarket notifications for each device, focusing on the risk inherent with the device and the disease being treated or diagnosed (e.g., devices with rapidly evolving technology or expansions of intended uses). See 63 FR 5387, 82 FR 17841. The Agency also considers the history of adverse event reports under the medical device reporting program for these devices, as well as their history of product recalls. *Id.*

As discussed in the April 16 notice, the January 15 notice (86 FR 4088) neither discussed the reserved criteria nor explained how HHS came to determine that the gloves no longer meet the reserved criteria; i.e., that the gloves are not intended for a use that is of substantial importance in preventing impairment of human health, or do not present a potential unreasonable risk of illness or injury. The January 15 notice contained no mention of or cite to this statutory

standard, nor an explanation as to why it was left out. The April 16 notice discussed other procedural and substantive deficiencies in the January 15 notice that contributed to HHS's and FDA's decision to reverse the determinations made in that notice. For example, the January 15 notice relied solely upon adverse event reports in the Manufacturer and User Facility Device Experience (MAUDE) as its basis for determining the products to be exempt from 510(k), and then only adverse event reports for a very narrow period of time. While adverse event reports are a valuable source of information, the reports have limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from adverse event reports alone, due to underreporting of events, inaccuracies in reports, lack of verification that the device caused the reported event, and lack of information about frequency of device use. Adverse event data is not adequate on its own for assessing safety, let alone whether to determine a device to be exempt from 510(k).

### III. Final Order Regarding Surgeon's Gloves and Patient Examination Gloves and Premarket Notification

In the April 16 notice, HHS and FDA announced our view that surgeon's gloves and patient examination gloves meet the reserved criteria, and sought comment on this determination. HHS and FDA received eight comments on that notice, all of which were supportive of the determination that surgeon's gloves and patient examination gloves meet the reserved criteria and are properly subject to premarket notification.

As discussed in the April 16 notice, because of their importance in preventing impairment of human health, FDA has long considered surgeon's and patient examination gloves to meet the reserved criteria under section 510(l) and to be subject to the 510(k) requirement. See 63 FR 5387, 63 FR 63222, 65 FR 2296. In 2017 and 2019, FDA evaluated all class I reserved devices to determine whether they continued to meet the reserved criteria. See 82 FR 17841, 84 FR 71794. FDA specifically evaluated the seven device types at issue based on its experiences with

510(k) submissions for the gloves, the risk inherent to the devices and the diseases they prevent, and other relevant considerations and determined that surgeon's gloves and patient examination gloves met the reserved criteria and therefore remained subject to premarket notification.

HHS and FDA continue to believe that these gloves are of substantial importance in preventing impairment of human health or present a potential unreasonable risk of illness or injury and thus are subject to the reporting requirement under section 510(k) of the FD&C Act. Based on the risks inherent to surgeon's gloves and patient examination gloves and the diseases being prevented, FDA's experience with these devices, and other relevant considerations, HHS and FDA have determined that gloves with the product codes LYY, LYZ, OIG, OPC, OPH, LZC, and OPA are intended for uses which are of substantial importance in preventing impairment of human health or present a potential unreasonable risk of illness or injury, and thus a report is required under section 510(k) of the FD&C Act. Surgeon's gloves and patient examination gloves are generally intended to prevent contamination and the spread of pathogens, and can be the key barrier protecting against spreading infection (Refs. 1-3). See 21 CFR 878.4460 and 880.6250. As set forth in the April 16 notice, surgeon's gloves prevent against contamination in the operating room (Refs. 4 and 5), medical gloves protect against occupational exposure, for example, to chemotherapy drugs (Refs. 6 and 7), and these gloves play an important role in protecting the public. Review under section 510(k) is necessary to provide reasonable assurance of their safety and effectiveness, including by helping to assure that the identified gloves are durable and impermeable, among other things.

Based on this evaluation and considering the comments submitted, HHS and FDA have made a final determination that surgeon's gloves and patient examination gloves meet the reserved criteria and therefore are subject to premarket notification.

#### IV. Further Information for Regulated Entities

The gloves discussed in this notice are reserved, and as such, a 510(k) is required for them. In general, FDA evaluates the dimensional and physical properties of the gloves, and

nonclinical data regarding barrier performance, biocompatibility, and residual powders, among other information, to support the safety and effectiveness of the gloves for their intended use. FDA also evaluates the indications for use and labeling to ensure the devices are appropriately labeled, consistent with their intended use. For any gloves that are distributed--including any gloves that are presented for import--after the compliance date of this order without premarket review, the Agency will consider and take appropriate enforcement action, taking into account the enforcement policy in its Guidance for Industry, “Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency; Guidance for Industry and Food and Drug Administration Staff” (Ref. 8).

## V. References

The following references marked with an asterisk (\*) are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. \*Centers for Disease Control. “Perspectives in Disease Prevention and Health Promotion Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings.” *Morbidity and Mortality Weekly Report* 1988; 37(25):377-388.

2. World Health Organization. Glove Use Information Leaflet. 2009.  
[https://www.who.int/gpsc/5may/Glove\\_Use\\_Information\\_Leaflet.pdf](https://www.who.int/gpsc/5may/Glove_Use_Information_Leaflet.pdf).

3. \*Collins, A. S. “Preventing Health Care-Associated Infections.” In: Hughes, R. G., editor. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD):

Agency for Healthcare Research and Quality (US); 2008 April. Chapter 41.

[https://www.ncbi.nlm.nih.gov/books/NBK2683/pdf/Bookshelf\\_NBK2683.pdf](https://www.ncbi.nlm.nih.gov/books/NBK2683/pdf/Bookshelf_NBK2683.pdf).

4. Alexander, J. Wesley, Joseph S. Solomkin, and Michael J. Edwards (2011).  
“Updated Recommendations for Control of Surgical Site Infections,” *Annals of Surgery*,  
253(6):1082-1093.
5. Sugarbaker, P. H. (2018). “Increased Safety of Surgical Glove Application: The  
Under/Over Method” *Annals of the Royal College of Surgeons of England*, 100(4):339-340.
6. Landeck, L., E. Gonzalez, and O. M. Koch. “Handling Chemotherapy Drugs--Do  
Medical Gloves Really Protect?” *International Journal of Cancer*. 2015 October  
15;137(8):1800-5. doi: 10.1002/ijc.29058. Epub 2014 July 22. PMID: 24978061
7. Nalin, M., G. Hug, E. Boeckmans, C. Machon, et al. “Permeation Measurement of 27  
Chemotherapy Drugs After Simulated Dynamic Testing on 15 Surgical And Examination  
Gloves: A Knowledge Update.” *Journal of Oncology Pharmacy Practice*. 2020 Aug  
26:1078155220950423. doi: 10.1177/1078155220950423. Epub ahead of print. PMID:  
32847481.
8. \*FDA Guidance, “Enforcement Policy for Gown, Other Apparel, and Gloves During  
the Coronavirus Disease (COVID-19) Public Health Emergency, Guidance for Industry and  
Food and Drug Administration Staff,” March 25, 2020, available at  
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health>.



Dated: July 12, 2021.

**Janet Woodcock,**

*Acting Commissioner of Food and Drugs.*

Dated: July 21, 2021.

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Xavier Becerra,

Secretary, Department of Health and Human Services.

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